

17 August 2023

Knowledge Ecology International
ATTN: Mr. James P. Love
Suite 511
110 Maryland Avenue NE
Washington, DC 20002

[VIA EMAIL \(james.love@keionline.org\)](mailto:james.love@keionline.org)

IN RE: FR Doc. 2023–17256 Filed 8–10–23; 8:45 am, entitled *Prospective Grant of an Exclusive Patent License: Manufacture, Distribution, Sale and Use of T-Cell-Based Immunotherapies for Solid Tumors*

Dear Mr. Love:

Thank you for providing us with your comments regarding the notice of the proposed license that the National Institutes of Health (“NIH”) intends to grant to EnZeta Immunotherapies, Inc. Prior to posting a notice for a proposed grant of an exclusive license, the NIH determined that all of the relevant criteria set forth in 37 C.F.R. §404 have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government’s intellectual property in the fields of use as specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We will consider all timely comments (*i.e.*, comments received on or before 28 August 2023) prior to executing the proposed license.

Turning to KEI’s queries 1 – 4, 6 and 10 - 11, we have determined that these queries either call for or inextricably implicate business confidential information that NIH is legally precluded from divulging. In addition, regarding query 11, NIH cannot speak for FDA. This technology is currently not licensed.

Turning to KEI’s query 5, we have received confirmation that the proposed licensee intends - depending of course on the outcome on high-risk clinical trials, certain of which may implicate special local regulatory and/or other circumstances - to make one or more licensed inventions available both in the U.S. and ex-U.S. The remainder of your query 5 either calls for or inextricably implicates business confidential information that NIH is legally precluded from divulging.

Turning to KEI’s query 7, the technology is early stage.

Turning to KEI’s query 8, NIH cannot speak for the government of the United States as a whole with respect to clinical trials, but we are not aware of any.

Turning to KEI’s query 9, NIH has answered this question many times previously. We cannot comment on specific license negotiations.

If your organization is requesting documents, such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests: www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests

Sincerely,

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